(c) whether it is also a fact that a Minister of Punjab Government had been monitoring the operation of these units and if so, what is Government's reaction in regard thereto?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI RAM VILAS PASWAN): (a) Yes, Sir. The State Government of Punjab has reported that recently they have detected a unit in village Ena-Khera, Tehsil Malout, Distt. Muktsar, manufacturing and supplying 'Bone Meal' a fertilizer covered under the Fertilizer Control Order (FCO), 1985, without obtaining the Dealer Registration Certificate (DRC)/Memorandum of Intimation, from Director (Agriculture), Punjab under the FCO.

Also, in the past, an enquiry had been conducted by the Vigilance Department, Punjab in respect of six Single Super Phosphate (SSP) manufacturing units located in that State for allegedly claiming concession fraudulently under the concession scheme from Government of India.

(b) FIR No.132, dated 27/10/2004 has been registered under the Police Station Malout, Distt. Muktsar against the above-mentioned unit located in Ena-Khera and three persons have been arrested under Section 7 of Essential Commodities Act (ECA) and subsequently released on bail.

The investigation could not substantiate charges against three SSP units. From one of the units, recovery of Rs. 18.35 lakh was effected. Investigation in respect of ether three units is in progress.

(c) As per the State Government of Punjab, no Minister of the State Government is involved in the operation of the 'Bone Meal' units.

Phase lllclinical trials

878. SHRI K. RAMA MOHAN RAO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the Government have decided to make Phase III clinical trials mandatory for imported EDNA biotech drugs;

(b) if so, the details thereof;

(c) whether any drug has been identified for clinical trials on recombinant drugs; and

(d) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Application for import of rDNA biotech drugs are examined as perthe provision made under Drugs & Cosmetics Act and Rules thereunder. In respect of imported rDNA biotech drugs for which marketing approval is sought, the decision regarding Phase III clinical trial is taken based on the available information in respect of regulatory status of product, published data on safety, quality efficacy and end use of the drugs marketing authorization, other country's approval etc.

Unlike other pharmaceuticals, rDNA biotech drugs also require approval of Genetic Engineering Approval Committee (GEAC), as per the rules framed under the Environment Protection (EP) Act, 1986, of the Ministry of Environment and Forests, for its safe release of drugs into environment.

(c) and (d) The following imported rDNA biotech drugs have been indentified for conducting Phase III clinical trial in the country:

1. r Human insulin Glulisine APIDRA inj.,

2. r Human Granulocytes colony stimulating factor inj.,

3. r Human Erythrpoietin inj.,

4.4l Human Interleukin IL3 inj.

Spurious drugs

†879. SHRI RAM JETHMALANI:
SHRI RAJ MOHINDER SINGH MAJITHA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government's attention has been drawn to the Report of World Health Organisation (WHO) stating that 35 per cent of the spurious drugs produced in the world are being manufactured in India;

(b) if so, whether Government have gathered any facts in this regard; and

(c) if so, the details thereof and steps taken and proposed to be taken to curb this practice?

---

†Original notice of the question was received in Hindi.